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INTERNATIONAL PRELIMINARY EXAMINAT

(PCT Article 36 and Rule 70)

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/IL 03/00026

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/IL: 03/00026

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6	Δd	Iditional observations, if necessar	y:			₩.			
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•	/. F	Reasoned statement under Articitations and explanations supp	cle 35(porting	2) with rega such state	rd to novelty nent	, inventive	step or i	ndustrial ap	plicability;
	1. 9	Statement							
•	i	Novelty (N)	Yes: No:	Claims Claims	1-45,50-53,5 46-49,54	55-62			
	1	Inventive step (IS)	Yes: No:	Claims Claims	1-45,50-53, 46-49,54	55-62			
		Industrial applicability (IA)	Yes: No:	Claims Claims	1-62	•			
	2.	Citations and explanations		-		;			

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International application No.

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see separate sheet

Re Item I

Basis of the report

The documents mentioned in this International Preliminary Examination Report are numbered in accordance with the order they appear in the International Search Report.

The amendments filed with the telefax of the 01.12.03 comply with Article 34(2)b PCT, insofar as they do not introduce any subject-matter which extends beyond the application as originally filed. They are thus admissible.

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

As no search report has been established for the claims 63-77, the present opinion solely concerns the filed claimed 1-62.

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Lack of clarity is objected insofar as the conciseness requirement is not met by the claims. Actually, the term "concise" as it can be read in Art. 6 and Rule 6.1(a) PCT and in the PCT Guidelines PG-III 5.1, should be interpreted not only as a requirement to shorten each Claim individually, but also to reduce as much as possible the number of Claims.

The present invention relates to a method for freezing/thawing samples of larger dimensions compared to straws used for biological samples (e.g. semen) and to an apparatus therefor.

D1 describes a method for thawing biological specimens comprising a first step of warming the sample by exposing it to an intermediate temperature. The counterpart of this first step in the present invention is divided in 2 sub-steps, namely subjecting first the sample to a gradient of temperature until a part of the sample reaches the intermediate temperature and then exposing the sample to the intermediate temperature.

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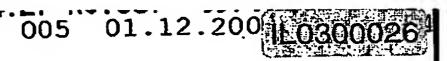
D2 relates to methods and apparatus for changing the temperature of a sample of the dimensions of a straw. The heat transfer within the sample perpendicularly to the axis of the straw can be considered to be uniform, due to the relatively small diameter of the sample. The device described in D2 appears to anticipate present claims 46-49 and 54, because the difference in sample size, which has an influence on how the device is constructed, does not appear in the present claims 46-49 and 54. The dimension of more than 0.5 cm in 2 perpendicular cross-sections is an essential feature of the present invention and is indeed directly linked the problem to be solved with respect to D2, i.e. to provide an apparatus for freezing larger (thicker) samples. All independent claims should contain this feature.

D3 relates to a method for freezing samples adapted for larger samples (over 50ml). This method implies 2 intermediate temperatures but not the use of an gradient of temperature.

With the exception of claims 46-49 and 54 as mentioned above, the present application fulfills the criteria of Article 33(2) PCT, because the claimed subject-matter is new with respect to the prior art as defined in Rule 64(1) to (3) PCT.

Assuming the lack of novelty above can be overcome, the present application would fulfill the criteria of Article 33(3) PCT, because the claimed subject-matter would involve an inventive step (Rule 65(1) and (2) PCT).

The present invention fulfills the criteria of Article 33(4) PCT, because the subject-matter of the present claims is industrially applicable.



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CLAIMS:

- 1. A method for changing the temperature of a sample from an initial temperature via an intermediate temperature to a final temperature, one of the initial and final temperatures being above the freezing point of said sample and the other being below the freezing point, the minimal dimension of the sample in each of two mutually perpendicular cross-sections exceeding 0.5 centimeters, and at least one of the cross-sections having an outer zone and an inner zone, the method comprising:
- (i) changing the temperature of the sample by subjecting it to a temperature gradient from the initial temperature to the intermediate temperature until the temperature of the sample in at least one part of the outer zone equals the intermediate temperature whilst the temperature of the sample in the inner zone or in another part of the outer zone, spaced from said one part, is different from said intermediate temperature;
- (ii) further changing the temperature of said sample by subjecting it to the intermediate temperature until the temperature of said sample in at least one cross-section is uniform and equals the intermediate temperature; and
- (iii) changing the temperature of said sample until the majority of said sample is at the final temperature.
 - 2. The method of Claim 1, wherein said sample is subjected in step (ii) to said intermediate temperature until the temperature of the sample equals said intermediate temperature.
 - 3. The method according to <u>anyone of Claims 1 or 25</u>, wherein the changing of the temperature in step (i) is achieved by moving the sample through a region with a <u>the</u> temperature gradient from the initial temperature to the intermediate temperature, and the changing of the temperature in step (iii) is achieved by moving the sample through a region with a temperature gradient from the intermediate temperature to the final temperature.
 - 4. The method of Claim 3, wherein said changing of the ambient temperature is at least partially gradual and is achieved at least partially by the gradual movement of said sample in the direction of a temperature gradient.